BRS Stakeholder To: Updates cc:

Sent by: Judy A Garrison Subject: APHIS Biotechnology Update 2

12/03/2003 02:35 PM

Dear BRS Stakeholder:

In the first stakeholder update that the U.S. Department of Agriculture's (USDA) Biotechnology Regulatory Services (BRS) sent out in October, we announced the formation of a new unit dedicated to ensuring compliance with the program's regulations and permit conditions. This second stakeholder update also announces the creation of a new unit within BRS: Environmental and Ecological Analysis (EEA).

EEA will team up with BRS' Plant Risk Assessment unit to process permits for field testing and deregulation that could have the potential to impact ecology or the environment. The unit will also analyze the overarching biological and ecological issues associated with agricultural biotechnology and field testing. The results of EEA's analysis will assist in the development of appropriate regulations, permit conditions, standards, and measures to mitigate or prevent identified risks to the environment and ecology.

BRS' new EEA unit will play an especially important role in the future as biotechnology companies seek to market pharmaceutical and industrial crops commercially, and as biotechnology research leads to the development of new varieties of genetically engineered (GE) crops, such as those resistant to drought or freezing temperatures. BRS must keep pace with new technology in order to safeguard American agriculture and the environment.

The new unit will also be tasked with ensuring that BRS' risk assessments and environmental assessments comply with all applicable environmental regulations and statutes, including the National Environmental Policy Act, The Endangered Species Act (ESA), Executive Orders, international treaties, etc. EEA will be the focal point for BRS in efforts to coordinate and communicate with other Agencies, such as the Environmental Protection Agency and the U.S. Fish and Wildlife Service (FW), to consider the impacts of biotechnology on ecology and the environment.

Dr. Susan Koehler, who has been with BRS since its inception and worked as a biotechnologist in USDA's Animal and Plant Health Inspection Service since 1994, was selected to head the new unit. Dr. Koehler's expertise includes plant biochemistry, physiology, and molecular biology as well as risk assessment of transgenic organisms. Dr. Koehler has reviewed applications for the introduction of transgenic organisms and assessed the biosafety of confined and unconfined environmental releases of transgenic organisms. Most recently she helped to develop conditions for field trials of pharmaceutical plants.

Dr. Koehler's team is made up of 2 Environmental Protection Specialists, an Ecologist, a Botanist, and a Virologist. Only one Ecologist position remains to be filled. EEA's new staff includes:

- **Bruce MacBryde Biotechnologist/Botanist:** Dr. MacBryde has been with BRS working as a biologist since the program was created. He has more than 20 years of experience working as a botanist at FWS on issues involving the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Prior to joining APHIS, he worked as a Research Botanist at the Nature Conservancy. Dr. MacBryde earned his Ph.D. in plant taxonomy at Washington University/the Missouri Botanical Garden.
- Michael Blanchette Environmental Protection Specialist: Mr. Blanchette has more than 14 years of experience working as an Environmental Protection Specialist for USDA's Agricultural Research Service (ARS) and the Army's Department of Environmental Quality. At ARS, Mr. Blanchette reviewed, analyzed, and interpreted environmental guidelines to identify impacts on Agency activities. He also evaluated Agency programs and facilities to ensure compliance with Federal, State, and local environmental regulations.
- Robyn Rose Ecologist: Before joining BRS, Ms. Rose worked at EPA's Office of Pesticide Programs, Biopesticides and Pollution Prevention Division where she analyzed scientific and regulatory data and conducted environmental risk assessments of biochemical and microbial pesticides. In addition, Ms. Rose is about to complete her Ph.D. at the University of Maryland where her research has focused on evaluating the potential nontarget effects of Bt sweet corn in comparison to conventional insecticide methods.
- Michael Wach Environmental Protection Specialist: Dr. Wach just completed his Ph.D. at Cornell University and has 7 years of research experience in the fields of plant pathology and weed science with an overall focus on plant protection. Dr. Wach also has an environmental law degree from the University of Oregon and 6 years of experience working on cases involving NEPA, the Clean Water Act, the Clean Air Act, and other environmental laws.
- **Michael Watson Biotechnologist/Virologist:** Prior to joining BRS, Dr. Watson worked as a Consumer Safety Officer at the Food and Drug Administration on issues involving biotechnology. He also spent more than 4 years with EPA where his primary focus was determining the safety of pesticides applied to food and bioengineered food products. Before receiving his Ph.D. at the University of California, Dr. Watson worked for ARS as a research plant pathologist.

To read the press release on the new unit, visit: http://www.aphis.usda.gov/lpa/news/press.html. In addition to making the public and our stakeholders aware of BRS' EEA unit, we're interested in hearing what overarching environmental issues you would like the new unit consider. Please e-mail any comments or suggestions to BRS@aphis.usda.gov.

Sincerely,
Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service